

Congress of the United States
Washington, DC 20515

February 5, 2016

Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Dr. Ostroff:

On January 26, 2016, President Obama called for the rapid development of tests, vaccines and treatments to fight the mosquito-transmitted Zika virus and the need to develop vaccines and therapeutics. To fulfill this goal, we believe that it is vital that the Food and Drug Administration (FDA) exercise its statutory authority by adding Zika to the FDA Tropical Disease Priority Review Voucher Program.

As you know, before Congress passed the “Adding Ebola to the FDA Priority Review Voucher Program Act” (P.L. 113-233) in 2014, Ebola was not listed in statute as a qualifying tropical disease. In addition to adding Filoviruses to the list of qualified tropical diseases, the new law provided the FDA more flexibility to add diseases to the qualifying list by issuing an order instead of a regulation. This flexibility was intended to eliminate unnecessary delays in offering appropriate incentives for companies to develop treatments for neglected tropical diseases that are emerging as new public health threats.

Unfortunately, today we are witnessing the spread of another tropical disease threatening the health of U.S. citizens. The Zika virus, transmitted primarily through mosquitos has spread rapidly in the Western hemisphere over the last year. Today, at least 31 states and two U.S. jurisdictions – the territories of Puerto Rico and the U.S. Virgin Islands – have reported instances of the virus. The recent outbreak has been linked with serious neurological disorders and life-threatening birth defects.

On January 28, 2016, the World Health Organization (WHO) reported that Zika is “spreading explosively” throughout the Americas and shortly thereafter declared it a global health emergency. Furthermore, the WHO found that as of today, cases have been reported in 23 countries in the region and that as many as four million people could be infected by the end of the year. WHO is concerned about this rapidly spreading disease due to the lack of immunity in newly affected areas, the wide geographical distribution of infected mosquitos, and the absence of any vaccines, treatments, or rapid diagnostic tests.

Given the lack of treatments available for Zika virus, we believe it is critical that FDA use its authority to add Zika to the list of Neglected Tropical Diseases eligible for the Priority Review Voucher program. FDA utilized this authority last year when adding two additional diseases, Chagas disease and neurocysticercosis, and as we learned from the Ebola crisis, it is critical to develop effective vaccines and treatments before an outbreak begins. This simple action by the FDA could spur development of an effective vaccine or treatment against Zika virus, and as a result save countless American lives.

We urge FDA to quickly exercise the authority provided by Congress to add Zika virus to the Neglected Tropical Disease list. Given the urgent nature of this matter, we would appreciate a response to this request no later than February 19, 2016.

We appreciate your attention to this important public health concern and look forward to your swift attention to this matter.

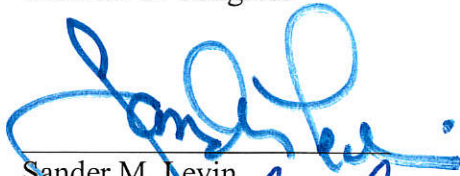
Sincerely,



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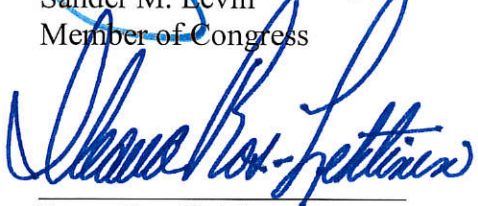
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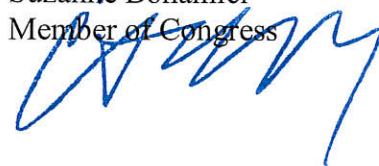
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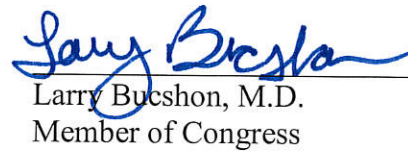


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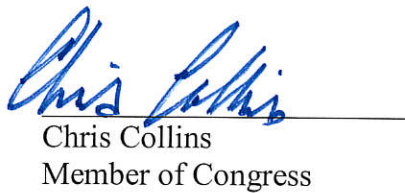
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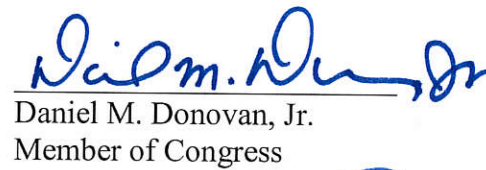

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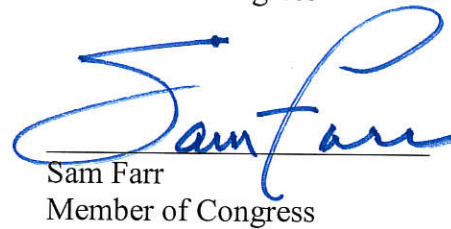

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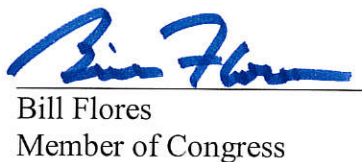

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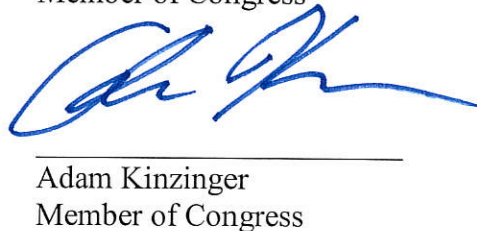

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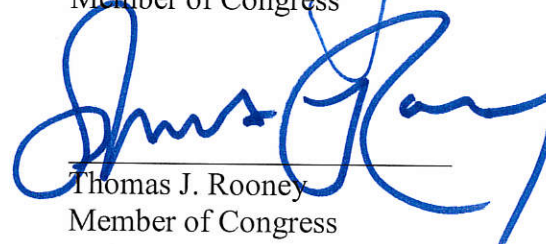

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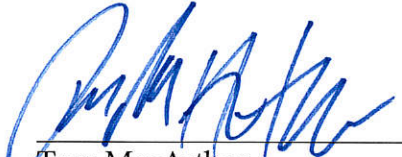

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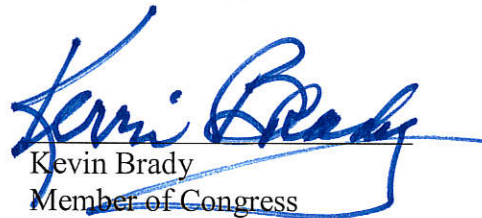

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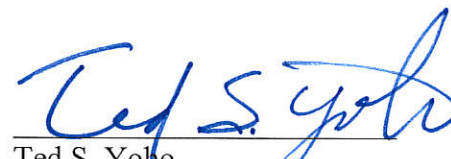

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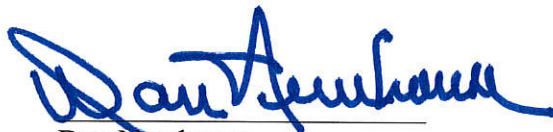
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